



CELG-042

In Re Application of:

Confirmation No.: 8455

Group Art Unit: 1614

Examiner: Raymond J. Henley III

For: Methods For Treatment Of Cognitive And Menopausal Disorders With D-Threo Methylphenidate

DATE OF DEPOSIT: October 20, 2006

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

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Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of


the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☒ Copies of reference numbers 209-222 listed on the attached Form PTO-1449 are enclosed herewith.

There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: *October 20, 2006*


Walter C. Frank
Registration No. 52,911

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439



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| Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office | Docket No. CELG-0422 | Application No. 10/820,397 |
| | Applicant Jerome B. Zeldis, et al. | |
| | Filing Date April 8, 2004 | Group 1614 |
| Confirmation No. 8455 | | |

NON-PATENT DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
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| /D.S./ | 209 | Aoyama et al., Kinetic Analysis of Enantiomers of threo-Methylphenidate and Its Metabolite in Two Healthy Subjects after Oral Administration as Determined by a Gas Chromatographic-Mass Spectrometric Method, 1990 , Vol. 79, No. 6, pp. 465-469 |
| | 210 | Arnold, L. E. et al., "A Double-Blind, Placebo-Controlled Withdrawal Trial of Dexamethylphenidate Hydrochloride in Children with Attention Deficit Hyperactivity Disorder," 2004 , <i>J. Am. Child Adolesc. Psychopharmacol.</i> 14(4):542-554 |
| | 211 | Ding, Y-S. et al., "Brain Kinetics of Methylphenidate (Ritalin) Enantiomers After Oral Administration," <i>Synapse</i> , September 2004 , 53, 168-175 |
| | 212 | Jaffe, P., "Will the real Ritalin please stand up?," <i>A Quarterly Newsletter by ad for Adults who have Attention Deficit Disorder</i> , 1992 , Issue #10, 3 pages |
| | 213 | Jarvi et al., "Bioequivalence of Methylphenidate Tablets," Abstract PPDM 8169, <i>Pharmaceutical Research</i> Vol. 7, No. 9, 1990 , 2 pages |
| | 214 | Meyer, et al., "Bioequivalence of Methylphenidate Immediate-Release Tablets Using a Replicated Study Design to Characterize Intrasubject Variability," <i>Pharmaceutical Research</i> , Vol. 17, No. 4, 2000 , 381-384 |
| | 215 | Patrick et al., "Distribution of Methylphenidate and P-Hydroxymethylphenidate in Rats," <i>Journal of Pharmacology and Experimental Therapeutics</i> , 1984 , Vol. 231, No. 1, 61-65 |
| | 216 | Patrick, K. S. et al., "New methylphenidate formulations for the treatment of attention-deficit/hyperactivity disorder," <i>Expert Opin. Drug Deliv.</i> , 2005 , 2(1), 121-143 |
| /D.S./ | 217 | Patrick, K.S. et al., Poster Abstract 267, "Synthesis, Pharmacology and Human Metabolic Formation of Ethylphenidate: the Transesterification Product of Methylphenidate and Ethanol," <i>The 56th Southeast Regional Meeting 2004</i> , November 10-13, 2004 , 2 pages |

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| NON-PATENT DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| /D.S./ | 218 | Quinn, D. et al., "Comparative pharmacodynamics and plasma concentrations of <i>d-threo</i> -methylphenidate hydrochloride after single doses of <i>d-threo</i> -methylphenidate hydrochloride and <i>d,l-threo</i> -methylphenidate hydrochloride in a double-blind, placebo-controlled, crossover laboratory school study in children with attention-deficit/hyperactivity disorder," November 2004 , <i>J. Am. Child Adolesc. Psychiatry</i> 43(11):1422-1429 | |
| | 219 | Silva, R. et al., "Open-Label Study of Dexmethylphenidate Hydrochloride in Children and Adolescents with Attention Deficit Hyperactivity Disorder," 2004 , <i>J. Child Adolesc. Psychopharmacol.</i> 14(4):555-563 | |
| | 220 | Volkow, N.D. et al., "Evidence That Methylphenidate Enhances the Saliency of a Mathematical Task by Increasing Dopamine in the Human Brain," <i>Am. J. Psychiatry</i> , July 2004 , 161(7), 1173-1180 | |
| | 221 | Weiss, M., et al., "A post hoc analysis of <i>d-threo</i> -methylphenidate hydrochloride (Focalin) versus <i>d,l-threo</i> -methylphenidate hydrochloride (Ritalin)," <i>J. Am. Acad. Adolesc. Psychiatry</i> , November 2004 , 43(11), 1415-1421 | |
| /D.S./ | 222 | Wigal, S., et al., "A double-blind, placebo-controlled trial of dexmethylphenidate hydrochloride and <i>d,l-threo</i> -methylphenidate hydrochloride in children with attention-deficit/hyperactivity disorder," <i>J. Am. Acad. Adolesc. Psychiatry</i> , November 2004 , 43(11), 1406-1414 | |
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